REMARKS

This paper is filed in response to the Office action mailed on March 26, 2008. In that Office action, the Examiner first notes that the amendment to the claims previously presented on May 23, 2007 does not comply with the requirements of 37 CFR 1.121(c) because the text of the withdrawn claims have been omitted. In response, applicants have hereby provided the original text for all previously withdrawn claims 1-8 and 21-30, and submit that the amendment is now in compliance with the requirements of 37 CFR 1.121(c).

In the outstanding Office action, the Examiner also objects to claim 9 for typographical errors, namely omitting the words "an" in line 14 and "than" in line 20 of the claim. Accordingly, applicants have hereby amended claim 9 and respectfully submit that the objection should be withdrawn.

Turning to the prior art rejections, claims 9-20 stand rejected under 35 U.S.C. 103(a) as being unpatentable over prior art. Specifically, claims 9, 13 and 18 stand rejected as being obvious over U.S. Patent No. 6,948,223 ("Shortt") in view of U.S. Patent No. 5,920,975 ("Morales"); claim 12 stands rejected as being obvious over Shortt in view of Morales and further in view of either U.S. Patent No. 5,147,302 ("Euteneuer"), or alternatively, International Application No. WO02/066095 ("Johnson"); claims 10 and 11 stand rejected as being obvious over Shortt in view of Morales and further in view of U.S. Patent No. 5,704,845 ("Miraki"); claims 14 and 15 stand rejected as being obvious over Shortt in view of Morales and further in view of U.S. Patent No. 6,629,350 ("Motsenbocker"); and claims 16-17 and 19-20 stand rejected as being obvious over Shortt in view of Morales and further in view of U.S. Patent No. 5,836,965 ("Jendersee"). Applicants respectfully disagree and traverse those rejections, as discussed more specifically in the paragraphs hereinafter.

Independent claim 9, as well as claims 10-20 dependent thereon, specifies a step of providing a balloon catheter 10, as shown in Fig. 4 below, comprising an inner tubular shaft 12 disposed within an outer tubular shaft 13, wherein the inner and outer shafts 12, 13 each have proximal and distal ends.

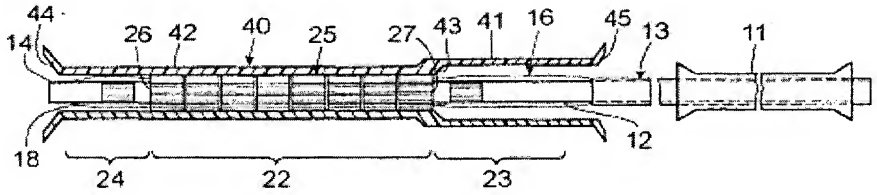

FIG. 4

The balloon catheter 10 is further provided with an inflatable balloon 16 having a proximal end attached to the outer shaft 13 near the distal end thereof and a distal end attached to the inner shaft 12 near the distal end thereof. Among other things, the method of claim 9 also recites a step of inflating the balloon 16 so that the proximal section 23 of the balloon inflates and engages the first section 43 of the stepped enclosure 40 *and* the stent 25. Claim 9 also requires the maximum outer diameter of the distal section 24 of the balloon to be no greater than the initial outer diameter of the stent 25.

On pages 3-5, items 5-7 of the Office action, the Examiner asserts that the prior art disclosed by Shortt combined with Morales provides each and every limitation of the method, as specified in claim 9. Alternatively, on pages 6-7, items 11-12 of the Office action, the Examiner asserts that the improved method disclosed by Shortt in combination with Morales also provides each and every limitation of the method as claimed.

The prior art disclosed by Shortt recites a process for mounting a stent using a series of tetrafluoroethylene (TFE) sheaths positioned over a stent/balloon assembly followed by a heat set operation. The process provides the assemblies of Figs. 1 and 2, as reproduced below.

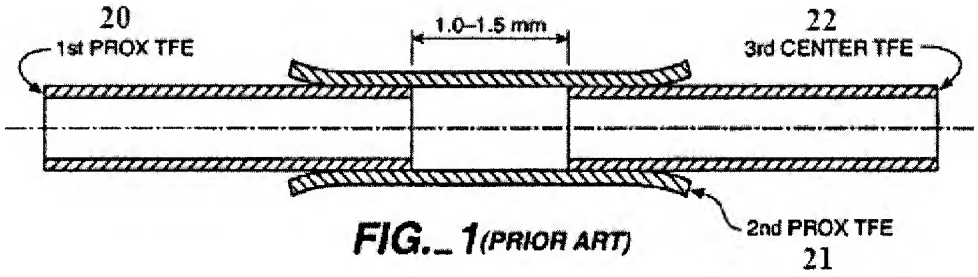

FIG. 1 (PRIOR ART)

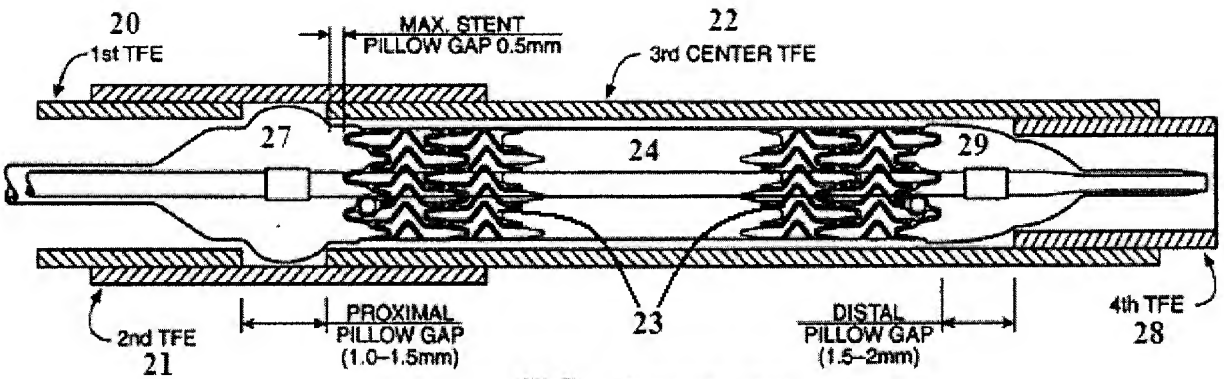

FIG._2 (PRIOR ART)

More specifically, column 2, lines 15-41 of Shortt discloses steps of crimping a stent 23 to a required size, and arranging the first, second and third TFE sheaths 20, 21, and 22, as shown in Fig. 1. The assembly of Fig. 1 and the stent 23 are then loaded onto a delivery system and positioned on a balloon 24. Subsequently, the TFE assembly of Fig. 1 is positioned over the stent/balloon assembly defining the proximal balloon pillow 27. A fourth TFE sheath 28 is then loaded onto the distal end of the assembly and positioned relative to the distal end of the stent 23 to define the distal balloon pillow 29. The completed assembly is shown in Fig. 2.

In item 5 of the Office action, the Examiner equates the second and third TFE sheaths 21, 22 of Shortt to the claimed first and second sections of the stepped enclosure, respectively. If this is in fact the case, then it is clear that Shortt fails to also provide an inner shaft disposed within an outer shaft as claimed. The TFE sheaths 21, 22 cannot serve as both the stepped enclosure and the inner and outer shafts. Additionally, the Examiner asserts that Shortt discloses the inner and outer shafts with reference to an element 30. However, there is no such element 30 in all of the Shortt disclosure. Furthermore, the prior art of Shortt fails to disclose an inflatable balloon having a proximal end attached to an outer shaft and a distal end attached to an inner shaft. Shortt also fails to disclose a step of inflating the balloon such that the proximal section of the balloon inflates and engages the first section of the stepped enclosure *and* the stent. As Fig. 2 of Shortt clearly illustrates, when inflated, the proximal balloon pillow 27 only engages the inner wall of the third TFE sheath 22 and not the stent 23. Specifically, the 'maximum stent pillow gap' of Fig. 2 prevents the proximal balloon pillow 27 from engaging the proximal sheath 23. In items 5 and 6 of the Office action, the Examiner additionally asserts that the prior art disclosed

by Shortt provides an inflated balloon with a distal section having a maximum outer diameter no greater than the initial outer diameter of the stent. However, as Fig. 2 of Shortt shows, the distal balloon pillow 29 clearly has a maximum outer diameter that is greater than the outer diameter of the stent 23.

Alternatively, Shortt discloses an improved method for mounting a stent onto a delivery system. More specifically, Short provides a mould assembly 10, as shown in Fig. 6 below.

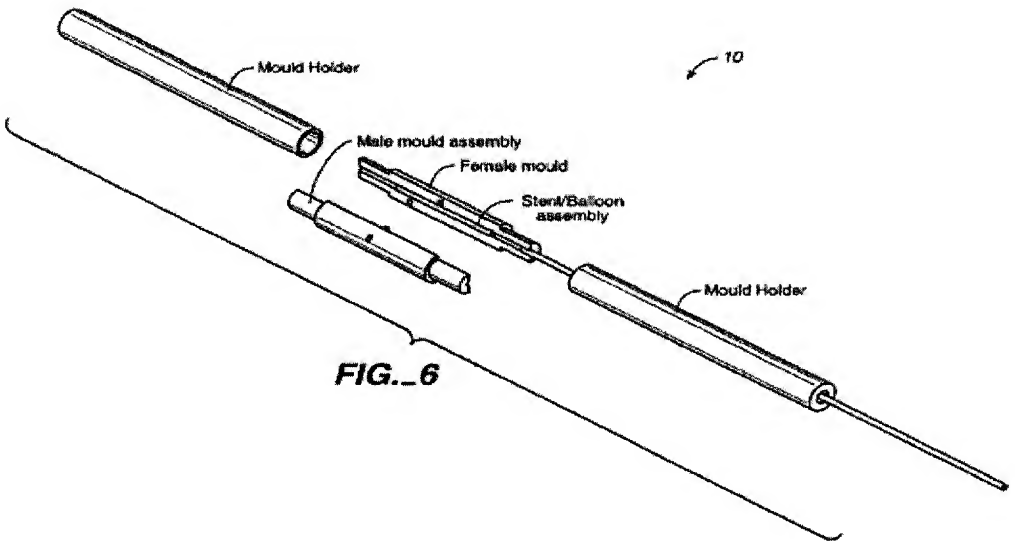

FIG._6

Column 4, lines 25-27 of Shortt further specifies that the male and female moulds interlock once the stent/balloon assembly has been inserted into the female mould. Subsequently, a heat set operation is applied to the mould and stent/balloon assembly to provide the delivery systems of Figs. 7A-7C provided below.

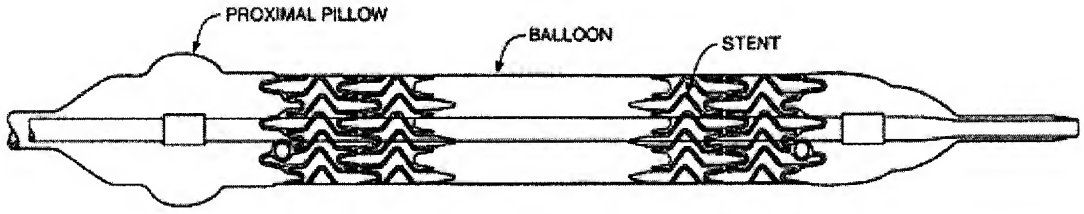

FIG._7a

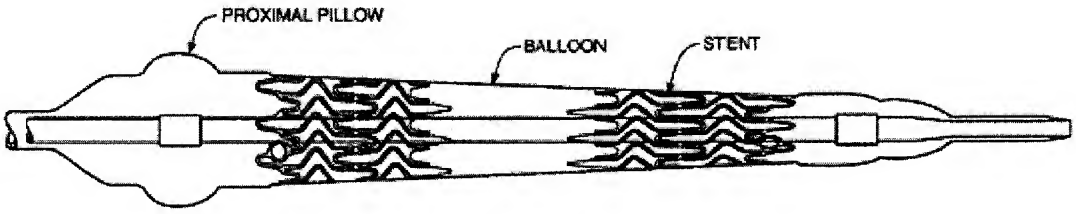

FIG._7b

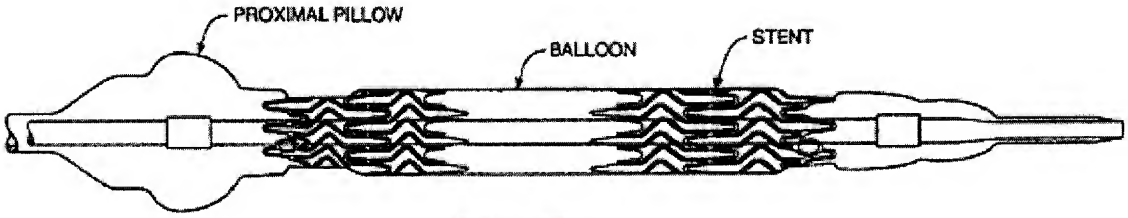

FIG._7c

In item 11 of the Office action, the Examiner refers to Figs. 7A-7C of Shortt and asserts that the improved method of Shortt provides the claimed balloon catheter, places a stent over the balloon, and places a stepped enclosure over the stent and balloon. However, the Examiner fails to address all limitations of the method as claimed. Specifically, Shortt still fails to provide a balloon catheter with an inner tubular shaft disposed within an outer tubular shaft, and an inflatable balloon having a proximal end attached to the outer shaft and a distal end attached to the inner shaft. Contrary to the Examiner's assertions, neither the figures nor the disclosure of Shortt provides the balloon catheter or a method for fabricating the balloon catheter as claimed.

Morales is directed specifically toward a tool and a method of using a tool for crimping a stent onto a catheter. More specifically, Morales discloses a method of rotating and constricting a coiled spring axially about a stent-catheter assembly. The constriction of the spring uniformly crimps a stent onto a balloon catheter. However, Morales fails to supply all of the deficiencies of Shortt discussed above. Specifically, Morales does not disclose a balloon catheter with an inner tubular shaft disposed within an outer tubular shaft, or an inflatable balloon with ends attached to the inner and outer shafts. Morales also fails to inflate a balloon such that the proximal section of the balloon engages a stent while the maximum outer diameter of the distal section of the balloon is no greater than the initial outer diameter of the stent.

As the combination of Shortt with Morales fails to disclose each and every element of the pending claims at issue, applicants respectfully submit that the obviousness rejection must fail and should be withdrawn.[1]

[1] To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations." MPEP §2143

CONCLUSION

In light of the foregoing, applicants respectfully submit that each of the currently pending claims, i.e. claims 9-20, are in a condition for allowance and respectfully solicit the same. If a telephone call would expedite prosecution of the subject application, the Examiner is invited to call the undersigned agent. The undersigned verifies that he is authorized to act on behalf of the assignee of the present application.

Dated: June 26, 2008

Respectfully submitted,

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